

## REMARKS

Reconsideration of this Application is respectfully requested. Claims 1-4, 7-10 and 12 are amended, without prejudice or disclaimer. Claims 1-12 are in this case.

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Initially, the Examiner rejected Claims 2 and 11 under 35 U.S.C. § 112, Second Paragraph, for indefiniteness. Specifically, she takes the position that Applicants' purported use of relative terminology in these Claims in referencing an object that is variable (i.e., the specific weight of internal organs, blood or other fluid) renders the Claims indefinite. (citations omitted).

The Examiner also rejected Claims 3-5, 9 and 12 under 35 U.S.C. § 112, Second Paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. According to the Examiner, there is insufficient antecedent basis for the limitation "the internal ones" in line 2 of Claim 3, or the limitation "the ball" on line 2 of Claim 4, line 1 of Claim 9, and line 1 of Claim 12.

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In response, Claims 3, 4, 9 and 12 are amended, replacing "internal ones" with - - inside - - and "the ball" with - - the locator - -, respectively, without prejudice or disclaimer, to better define the invention without limiting effect. Applicants, however, respectfully disagree with the Examiner's assertion that the terminology used, with reference to internal organs, blood or other body fluids, is improper. Indeed, we submit, Applicants' invention uses a novel locator construction that allows it to "float" at rather than sink in the surgical site, and this is accomplished by using a suitably configured

locator having specific weight generally lower than that of the internal organs, blood or other fluid present at the surgical site. While this feature inherently involves a range of specific weights that would allow a particular shape to “float”, such, we submit, is not tantamount to “relative terminology”.

Withdrawal of the Examiner’s rejections under § 112, Second Paragraph, is appropriate.

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In addition, the Examiner rejected Claims 1-12 under 35 U.S.C. § 101 on grounds that the claimed invention is directed to non-statutory subject matter. More particularly, she takes the position that the limitations “radio-opaque locator floating relative to internal organs, blood, or other fluids present at the surgical site” in Claims 1 and 10 are directed to, or include within their scope, a human being and, hence, are not patentable subject matter.

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During recent telephone communications with the Examiner regarding this issue, she indicated that Applicants’ insertion of the word - - for - - before “floating” would render moot her rejection under § 101. Independent Claims 1 and 10 are amended, accordingly, Claims 2-9 and 11-12 depending directly or indirectly therefrom. Applicants respectfully disagree that one or more elements of the Claims is/are a part of the human body. Rather, such language, we submit, provides reference point, the radio-opaque locator “floating” relative to the patient's internal organs, blood, etc.

Withdrawal of the Examiner’s rejection under § 101 is respectfully requested.

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Next, the Examiner rejected Claims 10 and 11 under 35 U.S.C. § 102(b) as allegedly anticipated by Yoon, U.S. Patent No. 6,248,088. According to the Examiner, with respect to Claim 10, Yoon discloses an organic fluid absorbing plug 16 for surgical use. Such plug, says the Examiner, comprises an elongated body constructed of a material having haemostatic properties. She also asserts that Yoon discloses the body connected to a radio-opaque locator 22. As to Claim 11, the Examiner finds that the alleged locator 22 of Yoon comprises at least one ball and is connected to the plug by a wire (the Examiner making reference to FIG. 7).

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Thereafter, the Examiner rejected Claims 1-9 under 35 U.S.C. § 103(a) as obvious and, thus, unpatentable over Yoon in view of Reynolds et al., U.S. Patent No. 6,673,080. The Examiner asserts, with respect to Claim 1, that Yoon discloses a surgical device for removing organic fluids from a body cavity. The device, the Examiner continues, comprises an absorbing plug 16, a tubular body 28 suitable for slidably housing the plug, and a plunger 30 slidably engageable in the tubular body so as to push the plug outside thereof and place it at the surgical site (the Examiner citing column 4, lines 49-60). In addition, the Examiner finds that the tubular body and plunger of Yoon have a distal end and a proximal end, wherein the plug is connected to a radio-opaque locator 22.

While the Examiner further argues that Yoon discloses removal of the plug, she admits that this reference fails to teach Applicants' "method and means" of removal (making reference to column 3, lines 52-54). As the Examiner also states, Yoon fails to disclose that, at the distal end of the plunger, a handle is provided for gripping the locator

to recover the plug after use by retracting it inside the tubular body. The Examiner then looks to the teachings of Reynolds et al. which, she says, disclose providing a handle 30 for gripping and recovering material by retracting a plunger inside a tubular body (the Examiner citing to FIG. 1 and column 2, lines 30-35).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to have provided a handle, as allegedly taught by Reynolds et al., in the device of Yoon to provide a means for removing the plug from the body.

With reference to Claim 2, the Examiner takes the position that the alleged locator 22 of Yoon comprises at least one ball and is connected to the plug by a wire (as purportedly shown in FIG. 7). As to Claim 3, while the Examiner acknowledges that Yoon does not disclose the size of the locator relative to the tube, she determined that it would have been obvious to one of ordinary skill in the art to have made the locator smaller than the inner dimensions of the tubular body such that the locator may pass through the tubular body during insertion and removal of the plug.

Turning now to Claims 4 and 5, the Examiner admits that Yoon fails to disclose a loop at the distal end of the plunger. She then looks to Reynolds et al. as purportedly teaching that it is well-known in the art to retrieve material from within the body using a loop at the end of a plunger to grasp and retract the material so that it may be extracted from the body. The Examiner also argues that Reynolds et al. disclose the loop formed by a relatively thin plate bent and connected at its ends to the distal end of the stem of the plunger (FIG. 1). She concludes that it would have been obvious to one of ordinary skill in the art to have provided a loop for grasping the locator, as suggested by Reynolds et al., because, she says, such is a well-known structure used in the retrieval of foreign

objects from the body. In addition, the Examiner finds that it would have been obvious to make the loop generally wider than the ball so that the loop would fit around it. Otherwise, says the Examiner, the loop could not function to retrieve the plug.

With respect to Claim 6, the Examiner asserts that Reynolds et al. provide, at the proximal end of the tubular body and of the stem, a handle for actuating axial sliding of the stem in one direction or the other as a result of corresponding pressure actions exerted simultaneously in opposite directions on the handle (the Examiner referring to Reynolds et al. - FIG. 1 and column 6, lines 21-35). This reference, the Examiner explains further, additionally discloses a handle of a ring type to allow engagement with the fingers of a user (citing FIG. 10), as allegedly set forth by Applicants' Claim 7.

The Examiner further argues, with regard to Applicants' Claim 8, that Reynolds et al. disclose that, at the proximal end of the tubular body, a pair of handle rings are provided, generally diametrically opposite to and coplanar with one another, whereas at the proximal end of the stem, a handle ring is allegedly provided, generally coplanar thereto (the Examiner making reference to FIG. 1).

Moreover, she takes the position that Yoon discloses that the plug is preferably white in color to provide contrast with surrounding tissue (citing column 5, lines 5-7), but acknowledges that this reference fails to teach a color of the locator or "ball" surface. The Examiner reasons that it would have been obvious to one of ordinary skill in the art to have also made the locator white or colored with a relatively light color to provide contrast with the surrounding tissue and fluids, as purportedly suggested by Yoon.

Last in the Office Action, the Examiner rejected Claim 12 under 35 U.S.C. § 103(a) as obvious and, therefore, unpatentable over Yoon. According to the Examiner, Yoon

discloses that the plug is preferably white in color to provide contrast with the surrounding tissue (allegedly at column 5, lines 5-7, in particular), while admitting that Yoon fails to describe the color of the locator or “ball” surface. She determines, however, that it would have been obvious to one of ordinary skill in the art to have also made the locator white, or colored with a relatively light color, to provide contrast with the surrounding tissue and fluids, as allegedly suggested by Yoon.

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Applicants, however, respectfully disagree with the Examiner’s reading and Application of the cited references.

First, we respectfully submit, the endoscopic device of Applicants’ invention novelly incorporates both a plug delivering device and a plug recovering device in a single instrument, which integrated combination is neither disclosed nor suggested by any of the references cited.

Second, although the Examiner seems to argue that tag 22 of Yoon corresponds with locator 10 of Applicants’ invention, tag 22 does not disclose nor does it suggest locating and recovering a plug in and from, respectively, a body cavity. To the contrary, tag 22 must be *larger* than the tube cross section and serves *only* to prevent the plug from escaping from the tube. Unlike Applicants’ invention, this arrangement makes the plug’s recovery both complicated and difficult.

This, we submit, is completely contrary to the locator ball of Applicants’ invention which must pass *through* the tube to reach the body cavity together with the plug.

Moreover, Applicants’ invention utilizes a ball, that is, locator 10, rather than a disk, i.e., tag 22 of Yoon. The advantages offered by Applicants’ ball-shaped locator is

considerable, especially the combination of its novel shape with a specific gravity that is lower than that of the surrounding fluid at the surgical site, allowing it to “float” rather than sink into the patient’s blood, tissues or bodily tissues. This is distinct and different from the teachings of Yoon whose *only* requirement for the disk shaped tag is that it be larger than the tube in order to avoid entering the same.

Furthermore, Yoon does not teach a locator designed to be dispensed, together with the plug, at the surgical site. Yoon, in addition, neither discloses nor does he suggest, nor would his teachings induce one skilled in the art to combine his plug with a basket device, as purportedly taught by Reynolds et al. This is because the plug of Yoon may *not* be separated from the endoscope. Hence, there is no need for a device that recovers the plug as the plug is simply retracted by grasping a tag to pull a cable to which the plug is attached.

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Applicant respectfully submits that none of the cited references, whether taken alone or in any combination, disclose or suggest Applicant’s invention, as claimed. Withdrawal of the Examiner’s rejections under §§ 101, 112, Second Paragraph, 102(b) and 103(a) is, therefore, respectfully requested.

The Specification and the Claims are amended to further comport with U.S. practice and, in so doing, to better define the invention without limiting effect, for clarity, consistency, and as a matter of desired style.

Applicant has made a good faith attempt to place this Application in condition for allowance. Favorable action is requested. If there is any further point requiring attention prior to allowance, the Examiner is asked to contact Applicants' counsel at (646) 265-1468.


Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, in an envelope with sufficient postage addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

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Name Grant E. Pollack

  
Signature



Grant E. Pollack, Esq.

Registration No. 34,097

POLLACK, P.C.

The Chrysler Building

132 East 43<sup>rd</sup> Street, Suite 760

New York, New York 10017

Telephone: (646) 265-1468

Facsimile: (646) 253-1276

E-mail: gpollack@pollackpc.com

Attorney for Applicants